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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2005N–0031]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Premarket Notification for a New Dietary Ingredient

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Fax written comments on the collection of information by [*insert date 30 days after date of publication in the* **Federal Register**].

ADDRESSES: OMB is still experiencing significant delays in the regular mail, including first class and express mail, and messenger deliveries are not being accepted. To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: Fumie Yokota, Desk Officer for FDA, FAX: 202–395–6974.

FOR FURTHER INFORMATION CONTACT: Peggy Robbins, Office of Management Programs (HFA 250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1223.

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SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Premarket Notification for a New Dietary Ingredient—21 CFR 190.6 (OMB Control Number 0910–0330)—Extension

Section 413(a) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 350b(a)) provides that a manufacturer or distributor of dietary supplements or of a new dietary ingredient is to submit information to FDA (as delegate for the Secretary of Health and Human Services) upon which it has based its conclusion that a dietary supplement containing a new dietary ingredient will reasonably be expected to be safe at least 75 days before the introduction or delivery for introduction into interstate commerce of a dietary supplement that contains a new dietary ingredient. FDA's regulations at part 190, subpart B (21 CFR part 190, subpart B) implement these statutory provisions. Section 190.6(a) requires each manufacturer or distributor of a dietary supplement containing a new dietary ingredient, or of a new dietary ingredient, to submit to the Office of Nutritional Products, Labeling, and Dietary Supplements notification of the basis for their conclusion that said supplement or ingredient will reasonably be expected to be safe. Section 190.6(b) requires that the notification include the following: (1) The complete name and address of the manufacturer or distributor, (2) the name of the new dietary ingredient, (3) a description of the dietary supplements that contains the new dietary ingredient, and (4) the history of use or other evidence of safety establishing that the dietary ingredient will reasonably be expected to be safe.

The notification requirements described previously are designed to enable FDA to monitor the introduction into the food supply of new dietary ingredients and dietary supplements that contain new dietary ingredients, in

order to protect consumers from unsafe dietary supplements. FDA uses the information collected under these regulations to help ensure that a manufacturer or distributor of a dietary supplement containing a new dietary ingredient is in full compliance with the act.

In the **Federal Register** of February 7, 2005 (70 FR 6444), FDA published a 60-day notice requesting public comment on the information collection provisions. No comments were received.

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

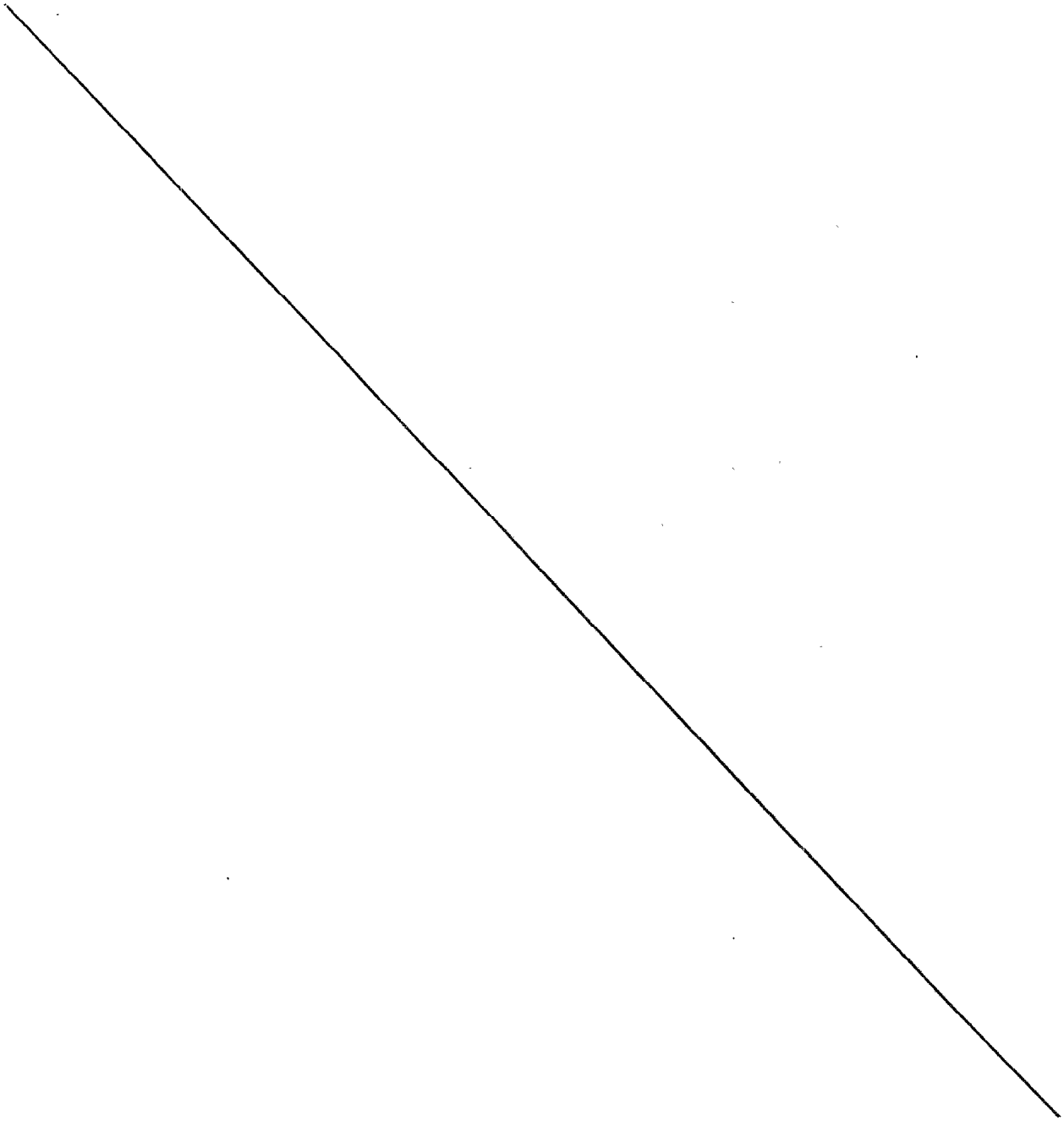
21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Respondent	Total Hours
190.6	71	1	71	20	1,420

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

The agency believes that there will be minimal burden on the industry to generate data to meet the requirements of the premarket notification program, because the agency is requesting only that information that the manufacturer or distributor should already have developed to satisfy itself that a dietary supplement containing a new dietary ingredient is in full compliance with the act. However, the agency estimates that extracting and summarizing the relevant information from the company's files, and presenting it in a format that will meet the requirements of section 413 of the act, will require a burden of approximately 20 hours of work per submission.

During the past 3 fiscal years, from October 1, 2002, through September 30, 2004, FDA received an average of 47 notifications per year with an average of 1 notification per submitting manufacture or distributor. In comparison, during the previous 3 fiscal years, from October 1, 1999, through September 30, 2001, FDA received an average of 23 notifications per year with an average of 1 notification per submitter. The annual average number of notifications FDA received during fiscal years 2002 to 2004 increased by 24. Because the

premarket notification program for new dietary ingredients is relatively new, the agency anticipates that this upward trend in receiving more notifications will continue over the next 3 fiscal years, from October 1, 2005, through September 30, 2007. Therefore, FDA estimates that the agency will receive



an annual average of 71 notifications with an annual average of 1 notification per submitter during fiscal years 2005 to 2007.

Dated: 4-26-05
April 26, 2005.

Jeffrey Shuren,
Assistant Commissioner for Policy.

[FR Doc. 05–????? Filed ??–??–05; 8:45 am]

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